WALSH PIZZI O'REILLY FALANGA

THREE GATEWAY CENTER
100 Mulberry Street, 15th Floor
Newark, NJ 07102
T: 973.757.1100
F: 973.757.1090
WALSH.LAW

Liza M. Walsh
Direct Dial: (973) 757-1101
lwalsh@walsh.law

December 29, 2023

VIA ECF
Hon. Julien Xavier Neals, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Hon. Faith S. Hochberg
Special Master
U.S. District Judge (ret.)
870 United Nations Plaza, Suite 12F
New York, New York 10017

Re: *Mylan Pharmaceuticals Inc. v. Teva Pharmaceuticals Industries Ltd., et al.*
Civil Action No.: 2:21-cv-13087 (JXN-JSA)

Dear Judge Neals and Judge Hochberg:

This firm, along with Goodwin Procter LLP, represents Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc. (collectively, "Teva") in the above-referenced matter. We write in connection with Teva's pending motion to dismiss the Complaint by Mylan Pharmaceuticals, Inc. ("Mylan") under Rule 12(b)(6). During the recent December 12 hearing before Judge Hochberg on Teva's motion, Mylan presented and erroneously relied upon the decision in *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, 650 F. Supp. 3d 269 (D. Del. 2023), which it had not previously raised in any of the briefing on Teva's motion to dismiss. Teva respectfully submits this brief response to Mylan's reliance on *Azurity* as supplemental authority.

In *Azurity*, the court addressed a motion to dismiss antitrust counterclaims brought by a generic company (Bionpharma) against a brand manufacturer (Azurity) based on Azurity's filing of seven distinct lawsuits regarding Bionpharma's generic product. 650 F. Supp. 3d at 274-75, 282. *Azurity* does not support allowing Mylan's case to go forward in any respect.

First, *Azurity* does not provide a basis for deeming Mylan's sham-petitioning claim timely, contrary to Mylan's argument at the hearing. *See* Hr'g Tr. 82-84. As Teva explained in its motion to dismiss, a sham-petitioning claim accrues when the relevant petition or lawsuit is filed. *See Perrigo Co. v. AbbVie Inc.*, 2021 WL 4551397, at *7-10 (D.N.J. Sept. 30, 2021), *aff'd*, 2022 WL 2870152 (3d Cir. July 21, 2022) (granting judgment on the pleadings and rejecting the plaintiff's argument that its claim for alleged generic delay from sham litigation did not accrue until the FDA approved the generic product); *see also* Teva Mot. 29 (collecting decisions). *Azurity* did not depart from that rule; in fact, that decision did not address a statute of limitations defense at all. Instead,

the court's passing discussion of "the accrual rule for antitrust damages" arose in the context of deciding whether sham-petitioning claims are compulsory counterclaims in a patent litigation lawsuit. 650 F. Supp. 3d at 277. Ultimately, the court concluded that it was "unnecessary" to resolve any issue related to accrual. *Id*.

Second, *Azurity*'s discussion of causation does not support allowing Mylan's petitioning claim to go forward. In *Azurity*, the plaintiff alleged that its FDA approval had been delayed by the filing of objectively unreasonable Hatch-Waxman litigation prompting an automatic 30-month stay, where the plaintiff secured FDA approval promptly after it won the patent litigation (just 3.5 months later) and where there had been no other independent regulatory bar to approval. 650 F. Supp. 3d at 279. The court's statement that an "allegation that the 30-month stay delayed [generic] entry must be accepted as true at the pleading stage," *id*. at 278, must be understood in the context of those allegations. The decision does not (and could not) suggest that mere "[t]hreadbare recitals of the elements of a cause of action," such as allegations that litigation ***caused*** delay, suffice to state a claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Instead, a plaintiff's factual allegations must be plausible. *Id*. And, as Teva has explained, Mylan's complaint fails to plausibly allege that Teva's Hatch-Waxman lawsuits and the resulting 30-month stays delayed FDA approval of Mylan's 20 mg or 40 mg products. *See* Teva Mot. 19-23; Teva Reply Br. 7-8. Here, the FDA did not approve Mylan's 20 mg product until October 2017—***five years after*** the 30-month stay expired and ***three years after*** the district court's injunction in the 20 mg lawsuit ended—even as the FDA approved Sandoz's 20 mg product in 2015 (two years earlier than Mylan's), notwithstanding the same challenged petitioning activity. *See* Teva Mot. 20-21. And as for the 40 mg product, Teva's statutory 3-year exclusivity for Copaxone 40 mg overlapped with the 30-month stay for all but two days, yet the FDA did not grant approval of Mylan's 40 mg GA for another eight months. Teva Mot. 23. These points—evident from the Complaint and judicially noticeable sources—do not "implicate[] a factual dispute," *cf*., *Azurity*, 650 F. Supp. 3d at 279, but cut directly to the heart of the plausibility of Mylan's delay theory—an issue entirely appropriate for resolution on a motion to dismiss.

Third, *Azurity* does not aid Mylan's efforts to avoid *Noerr-Pennington* immunity. As *Azurity* recognized, a plaintiff seeking to overcome *Noerr-Pennington* must plausibly allege the lawsuit or petition was (1) objectively baseless, and (2) constituted "an attempt to interfere directly with the business relationships of a competitor through the use of the government process—as opposed to the outcome of that process—as an anticompetitive weapon." 650 F. Supp. 3d at 279. The allegations in *Azurity* are nothing like those in Mylan's Complaint. In contrast to *Azurity*, *see id*. at 279-80, Mylan ***never*** alleges that Teva's Hatch-Waxman lawsuits, any other lawsuit referenced in the Complaint, or any of Teva's citizen petitions, were objectively baseless. *See* Teva Reply Br. 9. Nor, for that matter, has Mylan plausibly alleged how Teva's petitions and lawsuits could have harmed Mylan other than by Teva winning them—*i.e.*, through "the outcome of [the government] process." 650 F. Supp. 3d at 279; Teva Reply Br. 12.

Instead, Mylan has relied on the "serial-petitioning" exception to overcome *Noerr-Pennington* immunity, Teva Reply Br. 10-11. *Azurity* referenced that exception but did not rely on it. The plaintiffs there put forward allegations as to why the lawsuits "were objectively baseless for numerous reasons" that went beyond the bare outcome. 650 F. Supp. 3d at 279-81. The court merely referenced the existence of several lawsuits when assessing whether the plaintiffs had plausibly alleged subjective motivation. *Id.* at 281-82. The decision thus does not support Mylan's attempt to bypass the ordinary requirements for alleging sham litigation or petitioning.

In any event, and contrary to Mylan's argument at the hearing, *see* Hr'g Tr. 63-65, the "scope and breadth" (*id*. at 65) of the pattern of lawsuits and petitioning in *Azurity* is far different than alleged by Mylan. In *Azurity*, the brand company filed a total of seven lawsuits against a single generic entity regarding the same product. 650 F. Supp. 3d at 274-75, 282. By contrast, Mylan's theory of serial-petitioning depends on lawsuits filed years apart, based on ***different*** products, against ***different*** defendants (including a federal agency), in ***different*** jurisdictions (including foreign jurisdictions with their own patent laws). *See* Teva Reply Br. 11. Such temporally and topically dispersed proceedings against different defendants do not constitute a "series" in any meaningful sense—and do not remotely resemble the petitioning activity in *Azurity*.

Finally, *Azurity*'s discussion of antitrust injury is irrelevant to this case. The court concluded that the plaintiff had plausibly alleged antitrust injury based on litigation costs incurred in defending against alleged sham litigation. 650 F. Supp. 3d at 278. But in doing so, the court expressly rejected precedent in this District. As the District of New Jersey decision *Azurity* cites makes clear, for harm to an individual competitor to qualify as ***antitrust*** injury, it must be "tether[ed] … to harm borne by the market-at-large" and have "somehow harmed the competitive landscape." *Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 187 F. Supp. 3d 483, 486-87 (D.N.J. 2016). And here, Mylan does not allege any harm to itself—much less the competitive landscape—by virtue of litigation expenses incurred in any lawsuit Teva filed against Mylan. *See* Compl. ¶¶ 192-203, 216-32.[1]

Respectfully submitted,

s/Liza M. Walsh

Liza M. Walsh

cc: Counsel of Record (via ECF and Email)

[1] Mylan's Complaint does allege that "generic GA manufacturers" were "forced … to incur significant expenses" in connection with lawsuits Teva filed ***against the FDA***. Compl. ¶ 222. But as Teva has explained, Mylan was not "forced" to intervene; it chose to do so, rather than rely on government counsel to defend the FDA's prerogatives. Teva Mot. 63-64. That choice does not translate into an injury to the "competitive landscape," *Otsuka Pharm. Co.*, 187 F. Supp. 3d at 487, and nothing in *Azurity* suggests that such voluntarily incurred litigation expenses qualify as antitrust harm.